

REMARKS

Claims 1-7, 10-19, 21-24, and 39-52 are pending in the application, claims 8 and 9 being canceled and claims 51 and 52 being newly added herein. Claims 20 and 25-38 were previously canceled. Claims 1, 39, 47 and 51 are the only independent claims.

Interview Applicant wishes to thank the Examiner for the courtesy of the telephone interview of December 18, 2006. During that interview, proposed claim amendments were discussed and the plausibility of combining the cited Nakao reference with the Bates references. Applicant also explained how the present invention is directed to an instrument for performed polypectomies on both large polyps and small polyps. The same instrument can be used to sever a large polyp or a small polyp. The advantages of applicant instrument include an overall reduction in cost of snares to hospitals and a facilitation of polyp removal when two or more polyps of different sizes are found during a single intestinal investigation.

Specification

The specification has been amended herein to provide antecedent support for language inserted into the claims to more precisely describe the structure of the loop with respect to the notches, dents, indentations or dimples 32 and 34. The amendments to the specification and claims do not constitute the addition of new matter but merely serve to more particularly describe what is disclosed in the drawings. The amendments to the specification serve to more precisely define applicant's device and distinguish over the prior art particularly over U.S. Patent No. 6,348,056 to Bates. The notches or dents 32 and 34 of applicant's medical snare are of an ***order of magnitude smaller*** than the loop 18. An inspection of Figure 2 shows the width of applicant's loop 18 (in the relaxed or

unstressed fully expanded configuration) at the location of the notches or dents 32 and 34 as about **14 times** the width of each notch or dent 32 and 34 as measured along the same dimension. In contrast, in the Bates basket, the width of any one basket loop is only about **3 times** the width of each feature referred to by the Examiner as a notch or dent.

Claims Rejections - 35 U.S.C. §§ 102 and 103

Claims 1-7, 10-19, 21-24, and 39-50 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,348,056 to Bates et al. (“Bates ‘056”) in view of U.S. Patent No. 5,788,710 to Bates et al. (“Bates ‘710”).

Claims 8 and 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bates ‘056 in view of Bates ‘710 and further in view of U.S. Patent No. 5,782,840 to Nakao.

(A) In response to the Examiner’s rejection of the claims over Bates ‘056 and Bates ‘710, applicant has amended independent claims 1, 39 and 47 to clarify that applicant’s device is a ***cauterization polypectomy device***. To wit, the loop is not only made of an electrically conductive material for cauterizing organic tissues of a patient but is provided with a connector electrically linked to the loop for operatively coupling the loop to a voltage source.

(1) Neither Bates ‘056 nor Bates ‘710 discloses or suggests a polypectomy snare.

Those references are directed to stone retrieval baskets.

(2) Neither Bates ‘056 nor Bates ‘710 discloses or suggests a cauterization capability. There is no reason to use cauterization with a stone retrieval device. The conduction of electrical current to a target stone would have no effect on the target stone. More specifically, neither Bates ‘056 nor Bates

`710 discloses or suggests a loop provided with a connector electrically linked to the loop for operatively coupling the loop to a voltage source. Moreover, there would be no reason to provide such a connector in the device of Bates `056 or Bates `710 since electrical current would have no purpose or function in such a device.

(B) In further response to the Examiner's rejection of the claims over Bates `056 and Bates `710, applicant has amended independent claims 1, 39 and 47 (and several dependent claims) to further clarify the structure of the notches or dents (32 and 34). Those claims now specify that the recited notch or dent (32, 34) in the loop (18) is so small relative to the loop that the loop in its fully expanded configuration takes the form of a *single oval* (see applicant's Figure 2) having a width that is substantially unaffected by the notch or dent so that the loop in its fully expanded configuration can be used to sever a polyp substantially larger than any polyp severable by the smaller auxiliary loop formed by the distal end portion (36) of the loop. The purpose and function of applicant's cauterization snare is to enable severing of both large polyps and small polyps by the same instrument.

- (1) The stone retrieval basket of Bates `056 does not have an oval shape in its fully expanded configuration. Instead, the shape of the Bates `056 loop is the *dual-lobe configuration* of a figure 8 or two facing 3's (see enclosed Affidavit).
- (2) The device of Bates `056 could not be used for retrieving both large and small polyps, even if the device were modified to take the form of a single loop (rather than multiple loops disposed at different angles about an axis to form a

retrieval basket). The dual-lobe construction of each loop of the Bates stone retrieval basket could not be used in the expanded configuration to sever a large polyp. The inwardly projecting “notches” or “dents” are *so large* that they would detrimentally *interfere* with the placement of the expanded loop about a large polyp. In contrast to stones, polyps have the consistency of raw chicken liver and would be dangerously and irrevocably damaged by the inwardly projecting “notches” or “dents” of the Bates '056 loops.

Affidavit The enclosed Affidavit in support of patentability avers that the Bates loop design would never work in a polypectomy snare because when this loop is fully opened one would not be able to fit it around a large, soft polyp. The “indentations” between the two loop lobes are so severe that the fully expanded loop would never fit over a large, soft tissue mass. If such a snare were to be passed over a large polyp, it would surely scratch or otherwise injure the lesion. But what is more likely to occur is, the endoscopist would not be capable of passing such a snare over the polyp at all. There simply would not be enough room to fit the polyp into this “double 3 configuration”. Furthermore, the endoscopist operates within a confined space inside the colon lumen, where passing even a regular snare over a large polyp is not a simple maneuver. The “double 3 Bates configuration” would be virtually useless.

As further attested to in the enclosed Affidavit, applicant’s present snare invention is entirely novel over the Bates references because the two notches of applicant’s snare do not change the functional configuration of the snare: the state of the art cautery snare is oval shaped, with a transverse distance large enough to pass over the

polyp that is about to be transected. Applicant's snare, despite its two middle notches, maintains the general shape and functionality of a state of the art polypectomy snare. Thus, despite the two notches, when completely open, it may be easily passed over a large polyp. When a snare in accordance with applicant's invention is partially retracted into the catheter, the distal loop retains its ovoid shape because of the distal squaring off (by bends 52, 54). The notches (32, 34) alone would not do it. It is this novel design combination wherein (a) the two middle dents are configured in such a fashion that, when completely open the snare functions as a regular snare would, while (b) squaring off the distal end enables the formation of a perfectly functional ovoid smaller snare.

Claim 51 New claim 51 is a method claim reciting the use of the instrument of claim 1. As discussed above, neither Bates'056 nor Bates'710 suggests the use of such an instrument in alternatively severing both large and small polyps. In fact, Bates '056 teaches away from such a use because the device is intended to capture stones only in the partially retracted configuration shown in Figure 2 of the reference. The larger or fully expanded configuration of Figure 3 is used to enable release of a captured stone from the retrieval basket, not to capture a larger stone.

The claim amendments, if any, made herein are made without prejudice to applicants' right to pursue additional subject matter in a separate continuation or divisional application.

The present Amendment is submitted with a Request for Continued Examination, a request for a three-month extension of time, and a check in the amount of Nine-Hundred-and-Five Dollars (\$905) in payment of the Five-Hundred-and-Ten Dollar

(\$510) fee for a three month extension and the Three-Hundred-and-Ninety-Five Dollar (\$395) fee for requesting continued examination, both for a small entity.

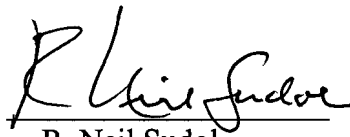
Conclusion

For the foregoing reasons, independent claims 1, 39, 47, and 51, as well as the claims dependent therefrom, are deemed to be in condition for allowance. An early Notice to that effect is earnestly solicited.

Should the Examiner believe that direct contact with applicant's attorney would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the number below.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

By: 
R. Neil Sudol
Reg. No. 31,669

714 Colorado Avenue
Bridgeport, CT 06605-1601
(203) 366-3560

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